

Claims

1) A vaccine comprising a viral capsid substantially incapable of replication in a patient and at least one antigen for co-administration with said capsid and against which it is desired to obtain an immune response, the vaccine formulated to induce, in a patient to whom the vaccine is administered, both:

- an antibody response against the co-administered antigen, and
- a T-cell response,

the at least one antigen and the viral capsid each being formulated separately or together and, when formulated separately, the vaccine being adapted to be administered as either separate formulations or as a mixture thereof.

2) A vaccine according to claim 1, wherein the viral capsid is not ALVAC.

3) A vaccine according to claim 1 or 2, wherein the viral capsid is a viral vector.

4) A vaccine according to any preceding claim, wherein the T-cell response is protective.

5) A vaccine according to any preceding claim wherein the viral capsid does not comprise a polynucleotide encoding an antigen, both the T-cell and antibody responses being induced to the at least one co-administered antigen.

6) A vaccine according to claim 5 wherein the T-cell response is induced to the co-administered antigen by the presence of the viral capsid.

7) A vaccine according to claim 5 or 6, wherein the antibody response induced in the presence of the vector is greater than that induced by the co-administered antigen alone.

- 8) A vaccine according to any of claims 1-4, wherein the viral capsid comprises a polynucleotide encoding a further antigen, the T-cell response being induced to the encoded antigen and the antibody response being induced to the co-administered antigen.
- 9) A vaccine according to claim 8, wherein the encoded antigen comprises at least one CD4⁺ or CD8⁺ epitope suitable for recognition by MHC molecules in the vaccinee.
- 10) A vaccine according to claim 8 or 9, wherein the encoded antigen and the co-administered antigen are homologous.
- 11) A vaccine according to claim 10, wherein the homologous encoded antigen and co-administered antigen share at least one common CD4⁺ or CD8⁺ epitope.
- 12) A vaccine according to claim 8 or 9 wherein the encoded antigen and the co-administered antigen are heterologous.
- 13) A vaccine according to claim 12, wherein the vaccine is a combination vaccine for inducing immune responses against antigens from the same pathogen.
- 14) A vaccine according to claim 12, wherein the vaccine is a combination vaccine for inducing immune responses against heterologous pathogens.
- 15) A vaccine according to any preceding claim, wherein the viral capsid induces a weak or negligible antibody response in the absence of the co-administered antigen.
- 16) A vaccine according to any preceding claim, wherein the viral capsid and the co-administered antigen are co-administered substantially co-temporaneously.
- 17) A vaccine according to any preceding claim, wherein the co-administered antigen and the viral capsid are administered as a mixture.

- 18) A vaccine according to any preceding claim, wherein the capsid is a poxvirus.
- 19) A vaccine according to any preceding claim, wherein the vaccine is suitable for administration in a homologous prime boost vaccination regimen.
- 20) A vaccine according to any preceding claim, wherein the vaccine is suitable for administration in a heterologous prime boost vaccination regimen.
- 21) A vaccine according to any preceding claim, wherein the viral capsid is an adenovirus.
- 22) A vaccine according to any preceding claim, wherein the capsid is MVA, or NYVAC.
- 23) A vaccine according to any preceding claim, wherein the capsid is a fowlpox virus.
- 24) A vaccine according to any preceding claim that induces both an effector T cell response and an antibody response to the at least one antigen, wherein the effector T cell response is not weaker than that induced by the viral capsid alone, and the levels of antibody induced are not lower than those induced by administration of the at least one antigen alone.
- 25) A vaccine according to any preceding claim, wherein the co-administered antigen is derived from *M. tuberculosis*, *Plasmodium sp*, influenza virus, HIV, Hepatitis B or C virus, Cytomegalovirus, Human papilloma virus, bacteria, *Plasmodium sp*, leishmania parasites or is derived from a tumour.
- 26) A vaccine according to claim 24, wherein the bacteria are Mycobacteria, H. influenza, pneumococcus or meningococcus.

- 27) A vaccine according to any preceding claim, wherein the co-administered antigen bacteria are Mycobacteria.
- 28) A vaccine according to any preceding claim, wherein the co-administered antigen is the Hepatitis B viral surface antigen, HBsAG.
- 29) A vaccine according to any of claims 8-29, wherein the encoded antigen is derived from *M. tuberculosis*, *Plasmodium sp*, influenza virus, HIV, Hepatitis B or C virus, Cytomegalovirus, Human papilloma virus, bacteria, *Plasmodium sp*, leishmania parasites or is derived from a tumour.
- 30) A vaccine according to any of claims 8-29, wherein the bacteria are Mycobacteria, H. influenza, pneumococcus or meningococcus.
- 31) A vaccine according to any of claims 8-30, wherein the co-administered antigen bacteria are Mycobacteria.
- 32) A vaccine according to any of claims 8-31, wherein the co-administered antigen is the Hepatitis B viral surface antigen, HBsAG.
- 33) A vaccine according to any preceding claim, wherein the antibody response to the co-administered antigen is greater than the antibody response induced by the administration of a vaccine comprising said antigen and alum, but without the capsid.
- 34) A vaccine according to any preceding claim, wherein the vaccine comprises alum, co-administered with the capsid.
- 35) A vaccine according to claim 18, wherein the poxviral capsid is an orthopox virus, the presence of an orthopox viral capsid inducing substantially equal ratios of Th-1 and Th-2 Helper T cells.

36) A vaccine according to claim 18, wherein the poxviral capsid is an avipox virus, the presence of an avipox viral capsid inducing a T cell mediated response, wherein the Th-1 Helper T cell response is greater than the Th-2 response.

37) A vaccine according to any preceding claim, wherein the co-administered antigen is not a polynucleic acid.

38) The use of a vaccine according to any preceding claim.

39) A method for stimulating both humoral and antibody responses to an antigen, comprising administration of the antigen to a patient in combination with a viral capsid, administration of the capsid and antigen being separately or together.

40) A kit comprising preparations of the antigen and capsid as defined in any preceding claim.

41) A vaccine for inducing an immune response to an antigen, the vaccine comprising the antigen and a vector, the vector in the absence of the antigen inducing a weak or negligible antibody response and in the presence of the antigen inducing a T cell response complementing the antibody response against said antigen, the vector and the antigen being formulated separately or together.

42) A method for inducing a combined T-cell and antibody response against at least one antigen in an animal in need thereof, the method comprising the steps of administering substantially co-temporaneously;

- a viral capsid incapable of replication in the animal, and
- said at least one antigen.

43) A method for inducing an immune response against at least one antigen in an animal in need thereof, the method comprising the steps of administering;

- a viral capsid incapable of replication in the animal, and

- said at least one antigen,

wherein the at least one antigen is co-administered with the capsid.

44) A method according to claim 43, wherein the immune response comprises a combined T-cell and antibody response to the at least one co-administered antigen.

45) A method according to claim 44, wherein the capsid comprises a polynucleotide encoding a further antigen.

46) A method according to claim 45, wherein the encoded antigen and the co-administered antigen are homologous and the immune response comprises a combined T-cell and antibody response to the antigen.

47) A method according to claim 46, wherein the encoded further antigen and the co-administered antigen are heterologous and the immune response to the at least one co-administered antigen comprises an antibody response, the encoded antigen inducing a T-cell response thereto.

48) A method according to any of claims 42-47, wherein the viral capsid and the at least one antigen are administered substantially co-temporaneously.

49) A vaccination method comprising co-administering an antigen together with a vector,
the method inducing both
- an antigen-specific T cell response to a poxvirus-encoded antigen, the encoded antigen being heterologous to the poxvirus and comprising a source of CD4⁺ and CD8⁺ epitopes;
and
- antibodies to the co-administered antigen.

50) A method of generating an antibody response to an antigen in a vertebrate vaccinee by co-administration, as a mixture, the antigen mixed with an orthopox virus.

- 51) A method according to claim 50 wherein the orthopox virus is replication-impaired.
- 52) A method according to claim 50 wherein the orthopox virus is of the modified vaccinia virus Ankara strain or NYVAC strain or a derivative of either.
- 53) A method according to any of claims 50-52 wherein the orthopox virus encodes the co-administered antigen or a homologous sequence.
- 54) A method according to any of 50-52 wherein the orthopox virus encodes an antigen that is heterologous to the co-administered antigen.
- 55) A method according to any of claims 50-52 wherein the vaccinee is a primate.
- 56) A method according to claim 55, wherein the vaccinee is a human.
- 57) A method according to any of claims 50-56, wherein the orthopox virus encodes a heterologous polypeptide antigen encoding a CD4+ and / or CD8+ T cell epitope against which the vaccinee has a pre-existing specific cellular immune response that was generated by a means other than by immunization with the said recombinant orthopox virus.